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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,203

07/29/2003

Thomas Thisted

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06/30/2006

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EXAMINER

PROUTY, REBECCA E

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/630,203	Applicant(s) THISTED ET AL.	
	Examiner Rebecca E. Prouty	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 33-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-26, 28-32 and 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/918,543.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

Claims 1-20 have been canceled. Claims 21-40 are at issue and are present for examination.

Applicant's election without traverse of Group I, claims 21-32 and 38-40, and the species of mutations of position 170 in the reply filed on 4/24/06 is acknowledged.

Claims 27 and 33-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/24/06.

Claims 26 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 22. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The only difference between claims 22 and 26 is they recite different sequences as the reference sequence for the amino acid numbers recited in the claims. However, the mutations recited in the list in both claims is identical.

Claims 30-32 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

Art Unit: 1652

particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 30 recites the broad recitation of at least 70%, and the claim also recites of at least 80%, of at least 90%, of at least 95%, of at least 97%, and of at least 99% which are narrower statements of the range/limitation. Similarly, claim 31 recites the broad recitation of hybridizes under low

Art Unit: 1652

stringency conditions and also recites hybridizes under medium stringency conditions and hybridizes under high stringency conditions which are narrower statements of the range/limitation and claim 39 recites the broad recitation of further comprises a *B stearothermophilus* alpha amylase and also further comprises a *B stearothermophilus* alpha amylase in a ratio of 1:10 to 10:1 and further comprises a *B stearothermophilus* alpha amylase in a ratio of 1:2 which are narrower statements of the range/limitation

Claim 32 is confusing in the recitation of "has altered stability, in particular at high temperatures from 70-120°C and/or low pH in the range from 4-6" as it is unclear if the variant must have altered temperature or pH stability or whether it can have only other stability characteristics altered e.g. altered oxidative stability.

Claims 21-26, 28-32 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of variant α -amylases having a mutation at the position corresponding to residue 170

Art Unit: 1652

of SEQ ID NO:8. The specification teaches the structure of only a few representative species of such variant α -amylases each with only a small number of altered amino acids compared to the parent α -amylases. However, the currently claimed genus includes variant α -amylases with any number of alterations of the parent enzyme as long as amylase activity is maintained. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having α -amylase activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 21-26, 28-32 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a variant of a parent α -amylase wherein said variant has at least 90% homology to SEQ ID NO:8, has α -amylase activity and comprises a mutation at the position corresponding to residue 170 of SEQ ID NO:8 does not reasonably provide enablement for any variant of any parent α -amylase wherein said variant has α -amylase activity and comprises a mutation at the

Art Unit: 1652

position corresponding to residue 170 of SEQ ID NO:8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 21-23, 26, 32, and 38-40 are so broad as to encompass any variant of any parent α -amylase wherein said variant has α -amylase activity and comprises a mutation at the position corresponding to residue 170 of SEQ ID NO:8. Claims 24, 25, and 28-31 further limit the scope of the parent α -amylase but do not in any way limit the number of mutations of said parent amylase that may be present. Thus, the currently claimed genus includes variant α -amylases with any number of alterations of the parent enzyme as long as amylase activity is maintained. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of variant α -amylases broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e.

Art Unit: 1652

expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to only a few representative species of such variant α -amylases each with only a small number of altered amino acids compared to the parent α -amylases.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any because the specification does not establish: (A) regions of the protein structure which may be multiply modified without effecting α -amylase activity; (B) a rational and predictable

Art Unit: 1652

scheme for major modifications to α -amylases at large numbers of residues with an expectation of obtaining the desired biological function; and (C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any variant of a parent α -amylase wherein said variant has α -amylase activity and comprises a mutation at the position corresponding to residue 170 of SEQ ID NO:8. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of α -amylases having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1652

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21, 22, 24-26, 28-31, 38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Outtrup et al. (WO 95/26397).

Outtrup et al. teach the α -amylases of *Bacillus* strains NCIB 12513 and NCIB 12512 each of which comprise a glutamine residue at the position corresponding to position 170 of SEQ ID NO:8 of the instant application. As such these α -amylases can be considered to be variants of the α -amylase of SEQ ID NO:8 or other α -amylases such as LE74, SEQ ID NO:6, SEQ ID NO:12 or SEQ ID NO:6 Δ I181, Δ G182. Outtrup et al. further teach detergent compositions comprising said α -amylases including compositions comprising other enzymes such as pullulanases. Therefore, Outtrup et al. anticipates all of the instant claims.

Claims 21, 24, 28, 30, 31, 38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Svendsen et al. (US Patent 5,989,169).

Art Unit: 1652

Svendsen et al. teach α -amylase variants in which amino acids 121-174 of *Bacillus amyloliquefaciens* α -amylase (SEQ ID NO:10 of the instant application) are replaced with amino acids 102-199 of Fungamyl (see column14, lines 61-68). As such this variant comprises a replacement of residue K168 (which corresponds to K170 of SEQ ID NO:8) with a serine residue. Svendsen et al. further teach compositions comprising said α -amylases including compositions comprising other enzymes such as glucoamylases and pullulanases. Therefore, Svendsen et al. anticipates all of the instant claims.

Claims 21, 24, 28-31, 38, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Andersen et al. (US PG-PUBS 2003/0129718)

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

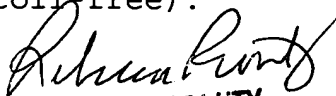
Art Unit: 1652

Andersen et al. teach α -amylase variants in which the amino acid corresponding to position 170 of *Bacillus licheniformis* α -amylase (SEQ ID NO:8 of the instant application) in any Termamyl-like α -amylase, including those of claims 24, 28-31 is replaced with a different amino acid. Andersen et al. also teach modification of other amino acid positions from the large group recited in the claims. Andersen et al. further teach compositions comprising said α -amylases including compositions comprising other enzymes such as glucoamylases and pullulanases. Therefore, Svendsen et al. anticipates all of the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).


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